Moreover, everolimus-eluting stents (EES) have not been compared with early generation sirolimus-eluting (SES) and paclitaxel-eluting stents (PES) in patients with LM disease.
Methods: Out of 12,339 consecutive patients, 11,941 completed last follow-up. 410 (3.4%) patients that underwent LM treatment (177 treated with EES and 233 with SES/PES) were compared with 11,531 (96.6%) patients that underwent non-LM treatment (3,924 treated with EES and 7,607 with SES/PES). In addition, clinical outcomes were stratified by stent type among LM and non-LM patients, respectively. Adjustment was performed with inverse probability of treatment weighting. Primary endpoint was a composite of cardiac death, myocardial infarction (MI), and target-vessel revascularization (TVR).
Results: At baseline, LM patients were older, had more frequently renal failure, LVEF<30%, cardiogenic shock, and smoking habits, and less frequently ACS compared with non-LM patients. At 4 years, LM patients had a higher risk of the primary endpoint compared with non-LM patients (34.7% vs 21.5%; HR 1.83, 95% CI 1.52-2.21). This was mainly driven by a higher risk of cardiac death (18.9% vs 7.3%; HR 2.96, 95%CI 2.28-3.84), whereas no significant differences were observed for MI (4.7% vs 5.4%; HR 0.93, 95% CI 0.52-1.65) and TVR (17.5% vs 14.0%; HR 1.31, 95% CI 0.99-1.73). Stratification of the primary endpoint by stent type showed a risk reduction with the use of EES compared with early generation SES/PES. This risk reduction was numerical among LM patients (30.2% vs 36.8%; HR 0.90, 95% CI 0.62-1.31) and met statistical significance among non-LM patients (18.5% vs 23.2%; HR 0.73, 95% CI 0.66-0.81), with no interaction between EES use and LM treatment (p-interaction=0.74).
Conclusions: LM patients have impaired clinical outcomes compared with non-LM patients during long-term follow-up, mainly due to a higher risk of cardiac death. Absence of significant interaction between EES use and LM treatment suggests that EES use has comparable impact on clinical outcomes in LM and non-LM patients.

TCT-42

Long-term Safety and Efficacy of Percutaneous Coronary Intervention With Stenting and Coronary Artery Bypass Surgery for Left Main Disease: Final Five-year Follow-up of the SYNTAX Trial

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Background: Current guidelines recommend coronary artery bypass graft surgery (CABG) when treating significant de novo LM stenosis; however, percutaneous coronary intervention (PCI) has a Class IIb indication for unprotected left main coronary artery (ULMCA). This analysis will compare the 5-year clinical outcomes in PCI- and CABG-treated LM patients in the SYNTAX trial.
Methods: In the SYNTAX trial, patients (N=1800) with left main and/or 3-vessel coronary artery stenoses were randomized to receive either PCI with TAXUS Express paclitaxel-eluting stents (PES) or CABG. The unprotected LM cohort (N=705) was a predefined subset.
Results: Four-year MACCE and the composite of death/stroke/MI were similar in ULMCA- PCI and CABG-treated patients (Table). Stroke was significantly increased in the CABG group and repeat revascularization was increased in the PCI arm at 4 years (Table). MACCE was similar between groups in patients with low or intermediate SYNTAX Scores (0-32: 29.0% vs 27.6%, p=0.65) but significantly increased in PCI patients with high scores (≥33: 26.3% vs 42.6%, p=0.003).

Adverse Event Rates in the LM cohort at 4 years

	CABG (n=348)	PCI (n=357)		CABG (n=348)	PCI (n=357)
MACCE	27.8%	33.2%	Stroke	4.3%	1.5%*
Death/ Stroke/MI	17.7%	17.1%	MI	4.8%	7.2%
Death	11.2%	11.4%	Repeat Revascularization	14.6%	23.5%*

MACCE: Major adverse cardiac and cerebrovascular events including all-cause death, stroke, myocardial infarction, repeat revascularization. Time-to-event rates at 4 years.
*p<0.05 from log-rank or chi-square test.

Conclusions: At 4 years, no difference in overall MACCE was found between treatment groups. There was an advantage of PCI in stroke and a reduced need for repeat revascularization with CABG. SYNTAX and other recent studies of LM disease suggest that in some patients (those with less complex lesions as defined by low or intermediate SYNTAX Scores), PCI using drug-eluting stents may be as effective but less invasive than CABG. CABG should be used for patients with more complex anatomical disease (high SYNTAX Scores). Five-year data will be available at the time of presentation.

TCT-43

Final Five-year Follow-up of the SYNTAX Trial: Optimal Revascularization Strategy in Patients with Three-vessel Disease

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Background: In patients with severe, multivessel coronary disease, coronary artery bypass grafting (CABG) has been considered the standard of care. We will present 5-year outcomes in the 3VD subgroup of patients in SYNTAX.
Methods: SYNTAX is a randomized clinical trial with nested registries. A cardiac surgeon and interventional cardiologist screened consecutive patients with de novo 3VD and/or LM disease. After informed consent, the patient was randomized if suitable for equivalent revascularization with either treatment; otherwise, they were enrolled in a nested registry. Analysis of the 3VD patient cohort was prespecified.
Results: In the 3VD subgroup at 4 years, MACCE was significantly higher in patients with percutaneous coronary revascularization (PCI) compared with CABG patients. The rates of composite death/stroke/MI, death, MI, and repeat revascularization were increased in PCI patients; however, stroke was similar between groups at 4 years (Table). Partitioning 3VD subgroup patients by SYNTAX Score tercile demonstrated similar MACCE in patients with low scores (0-22: CABG 24.7% vs PCI 30.4%, p=0.27); whereas both MACCE and mortality were increased in PCI patients with intermediate scores (23-32: 17.9% vs 33.3%, p<0.001 and 6.8% vs 12.7%, p=0.048), and with scores ≥33 (21.2% vs 37.9%, p<0.001 and 6.5% vs 14.5%, p=0.02). Five-year outcomes will be available at the time of the presentation.

Adverse Event Rates at 4 years in the 3VD cohort

	CABG (n=549)	PCI (n=546)		CABG (n=549)	PCI (n=546)
MACCE	21.0%	33.7%*	Stroke	3.4%	2.8%
Death/ Stroke/MI	12.6%	18.6%*	MI	3.3%	9.0%*
Death	7.3%	11.9%*	Repeat Revascularization	10.2%	22.8%*

MACCE: Major adverse cardiac and cerebrovascular events including all-cause death, stroke, myocardial infarction, repeat revascularization. Time-to-event rates at 4 years.
*p<0.05 from log-rank or chi-square test.

Conclusions: This will be the first presentation of the final 5-year outcomes in the 3VD patient population of SYNTAX. Four-year results suggest that CABG remains the standard of care for patients with complex lesions (intermediate or high SYNTAX Score). With less complex disease (low SYNTAX Scores), PCI is an acceptable revascularization alternative.

TCT-44

LEADERS: 5-Year Follow-Up from a Prospective, Randomized Trial of Biolimus A9-Eluting Stents with a Biodegradable Polymer vs. Sirolimus-Eluting Stents with a Durable Polymer- Final report of the LEADERS study

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Background: The effectiveness of 1st generation durable polymer drug-eluting stents comes at the expense of delayed arterial healing and subsequent late adverse events such